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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,875	03/08/2004	Keith G. Lurie	016354-005213US	2670

20350 7590 11/01/2005

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EXAMINER	
PATEL, NIHIR B	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,875	LURIE ET AL.	
	Examiner	Art Unit	
	Nihir Patel	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 8th, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04.06.2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1, 3 and 7 through 16** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim **1** of copending Application No. 10/660,462. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between **claims 1 and 3** of the current application and claims **1 and 10** of copending application 10/660,462 lies in the fact that the copending application 10/660,462 includes many more elements and is thus much more specific. Thus claim 1 of copending application 10/660,462 is in effect a "species" of the "generic" claim 1 of the current application. It has been held that the generic invention is "anticipated" by the "species". See ***In re Goodman,*** 29 USPQ2d 2010 patentably distinct from claim 1 of the copending application. **With respect to claim 7 of the current application,** the limitations can be found in claim 3 of the copending application 10/660,462. **With respect to claim 8 of the current application,** the limitations can be found in claim 4 of the copending application 10/660,462. **With respect to claim 9 of the current application,** the limitations can be found in

claim 5 of the copending application 10/660,462. **With respect to claim10 of the current application,** the limitations can be found in claim 6 of the copending application 10/660,462. **With respect to claim 11 of the current application,** the limitations can be found in claim 7 of the copending application 10/660,462. **With respect to claim 12 of the current application,** the limitations can be found in claim 8 of the copending application 10/660,462. **With respect to claim 13 of the current application,** the limitations can be found in claim 9 of the current application 10/660,462. **With respect to claim 14 of the current application,** the limitations can be found in claim 11 of the copending application 10/660,462. **With respect to claim 15 of the current application,** the limitations can be found in claim 12 of the copending application 10/660,462. **With respect to claim 16 of the current application,** the limitations can be found in claim 13 of the copending application 10/660,462.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **17 and 20** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/660,462 in view of Idris (US 5,685,298). **Claim 17 of the current application** limitations can be found in claim 1 of the copending application 10/660,462 except for claim 17, recites a means to interface with the patient's airway; Idris discloses an apparatus that does provide a means to interface with the patient's airway. Therefore it would have been obvious to modify the copending application 10/660,462 by providing a means to interface with the patient's airway in order to prevent leakage and obtain maximum treatment. **With respect to**

claim 20 of the current application, the limitations can be found in claim 9 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented..

The above provisional obviousness-type double patenting rejection also applies to

application: **10/426,161**
10/765,318
11/127,993
10/119,203
10/224,263
10/426,161
10/460,558
11/051,345
10/401,493

Claim **1** is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of **U.S. Patent No. 6,938,618**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between **claim 1** of the current application and claim 1 of patent '618 lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 1 of patent '618 is in effect a "species" of the "generic" invention of claim 1 the current application. It has been held that the generic invention is "anticipated" by the "species". **See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).** Since claim 1 of current application is anticipated by claim 1 of patent '618, it is not patentably distinct from claim 1 of patent '618. **With respect to claim 3 of the current application,** the limitations can be found in claim 2 of patent '618. **With respect to claim 4 of the current application,** the limitations can be found in claim 3 of patent '618.

The above obviousness –type double patenting rejection also applies to U.S. Patent No:

5,692,498
5,551,420
5,730,122
6,062,219
6,155,257
6,224,562
6,312,399
6,526,973
6,604,523
6,587,726
6,863,656

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1, 2, 3, 5-7, 11 and 13** are rejected under 35 U.S.C. 102(b) as being anticipated by Biondi et al. (US 5,377,671). **Referring to claim 1,** Biondi discloses a method that comprises delivering a positive pressure breath to the person **(see column 1 lines 20-30)**; extracting respiratory gases from the person's airway using a vacuum following the positive pressure breath to create an intrathoracic vacuum to lower pressure in the thorax and to enhance blood flows back to the heart **(see column 1 lines 20-30 and lines 50-55)**; and repeating the steps of delivering positive pressure breaths and extracting respiratory gases **(see column 1 lines 30-40)**.

Referring to claim 2, Biondi discloses a method wherein the person is suffering from ailments selected from a group consisting of head trauma, elevated intracranial pressures, low blood pressure, low blood circulation, low blood volume, cardiac arrest hypotension, shock, hypertension, intraocular pressures and heart failure **(see column 1 lines 16-19)**.

Referring to claim 3, Biondi discloses a method that further comprises regulating the amount of intrathoracic vacuum using a threshold valve that is in fluid communiation with the person's airway **(see column 3 lines 15-25).**

Referring to claim 5, Biondi discloses a method that comprises stopping application of the vacuum when applying the positive pressure breath using a switching arrangement.

Referring to claim 6, Biondi discloses a method wherein the positive pressure breath is delivered using source selected from a group consisting of a mechanical ventilator, a hand held bag valve resuscitator, mouth-to-mouth, or a means to provide intermittent positive pressure ventilation **(see column 1 lines 15-20).**

Referring to claim 7, Biondi discloses a method wherein the respiratory gases are extracted with a constant extraction, varied over time, or a pulsed extraction.

Referring to claim 11, Biondi discloses a method wherein the vacuum is maintained with negative flow or without flow.

Referring to claim 13, Biondi discloses a method wherein the positive pressure breath is extracted using equipment selected from a group consisting of a mechanical ventilator, a vacuum with vacuum regulator, a phrenic nerve stimulator, an extrathoracic vest, a ventilator bag and an iron lung cuirass device **(see column 1 lines 15-20).**

Claims **17, 18, 21, 23 and 24** are rejected under 35 U.S.C. 102(b) as being anticipated by Alferness (US 4,349,015). **Referring to claim 17,** Alferness discloses an apparatus that comprises a means to interface with the patient's airway **22, 26 and 42 (see figures 1 and 2)**; a means to repeatedly extract respiratory gases from the patient's lungs and airway to create and periodically maintain a negative intrathoracic pressure **(see column 5 lines 28-68 and column 6**

lines 1-56); a means to repeatedly regulate the extraction of respiratory gases within the patient's lungs and airway **(see abstract)**; and a means to deliver a positive pressure breath, to periodically provide inspiration of respiration gases **(see column 4 lines 35-50)**.

Referring to claim 18, Alferness discloses an apparatus wherein the means to extract respiratory gases comprises vacuum source selected from a group consisting of a suction line or venture device attached to an oxygen tank **(see column 4 lines 34-40)**.

Referring to claim 21, Alferness discloses an apparatus wherein the means for regulating comprises a threshold valve that is in fluid communication with the person's airway **(see column 4 lines 40-45)**.

Referring to claim 23, Alferness discloses an apparatus wherein the positive pressure breath is delivered using source selected from a group consisting of a mechanical ventilator, a hand held bag valve resuscitator, mouth-to-mouth, or a means to provide intermittent positive pressure ventilation **(see column 4 lines 34-40)**.

Referring to claim 24, Alferness discloses an apparatus that comprises a housing having an interface that is adapted to couple the housing to the person's airway **22, 26 and 42 (see figures 1 and 2)**; a vacuum source in fluid communication with the housing for repeatedly extracting respiratory gases from the person's lungs and airway to create and periodically maintain a negative intrathoracic pressure **(see column 4 lines 34-40)**; a vacuum regulator to regulate the extraction of respiratory gases from patient's lungs and airway **(see column 4 lines 15-25)**; and a positive pressure source in fluid communication with the housing for intermittently supplying positive pressure breaths to the person **(see column 4 lines 34-40)**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims **4, 8-10, 12 and 14-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Biondi et al. (US 5,377,671). Biondi discloses the applicant's invention as claimed with the exception of disclosing the ranges of different system parameters, such as breath delivery time and date, vacuum pressure and intrathoracic pressure levels. At the time of the invention was made, it would have been obvious to one having ordinary skill in the art to optimize the most effective variables of this method to achieve optimal results, such as reducing intracranial pressures. Therefore it would have been obvious to modify the method of Biondi by utilizing the specific ranges of breath delivery time and rate, vacuum pressure and intrathoracic pressure levels because it is well known in the art to provide different parameters of breath delivery time. Also the system parameters would be varied on patient criteria such as age of the user, disease, process, disease to be treated in order to provide appropriate ventilation which would be obvious to one of ordinary skill in the art.

Claim **22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness (US 4,349,015). Alferness discloses the applicant's invention as claimed with the exception disclosing actuating pressure ranges. It would have been obvious to of ordinary skill in the art at the time the invention was made to arrive at the claimed pressure ranges, based on the teachings of Alferness **"that those skilled in the art will accordingly recognize that the predetermined**

value of pressure that is required to open the valve may be empirally varied to fit a specific design and opening mode of the apparatus." Also, the actuating pressure of the valve would be varied on patient criteria such as age of the user, disease process, disease to be treated because these factors would increase/decrease the actuating pressure needed in the valve system to provide appropriate ventilation which would be obvious to one of ordinary skill in the art.

Claims **19 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness (US 4,349,015) in view of Biondi (US 5,377,671). **Referring to claim 20,** Alferness discloses the applicant's invention as claimed with the exception of providing means for extracting respiratory gases is selected from a group consisting of a mechanical ventilator, a vacuum with vacuum regulator, a phrenic nerve stimulator, an extrathoracic vest, a ventilator bag, and an iron lung cuirass device. Biondi discloses an apparatus that does provide means for extracting respiratory gases is selected from a group consisting of a mechanical ventilator, a vacuum with vacuum regulator, a phrenic nerve stimulator, an extrathoracic vest, a ventilator bag, and an iron lung cuirass device. Therefore it would have been obvious to modify Alferness's invention by providing means for extracting respiratory gases is selected from a group consisting of a mechanical ventilator, a vacuum with vacuum regulator, a phrenic nerve stimulator, an extrathoracic vest, a ventilator bag, and an iron lung cuirass device as taught by Biondi in order to improve the breathing process of the user.

Referring to claim 19, Alferness discloses the applicant's invention as claimed with the exception of providing a switching mechanism to stop the extraction of respiratory gases during delivery of a positive pressure breath wherein the switching mechanism is selected from a group consisting of mechanical devices, magnetic devices, and electronic devices. Biondi discloses an

apparatus that does provide a switching mechanism to stop the extraction of respiratory gases during delivery of a positive pressure breath wherein the switching mechanism is selected from a group consisting of mechanical devices, magnetic devices, and electronic devices. Therefore it would have been obvious to modify Alferness's invention by providing a switching mechanism to stop the extraction of respiratory gases during delivery of a positive pressure breath wherein the switching mechanism is selected from a group consisting of mechanical devices, magnetic devices, and electronic devices as taught by Biondi in order to provide better control of breathing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nihir Patel
October 27th, 2005

Henry Bennett
Supervisory Patent Examiner
Group 3700